IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

ALLERGAN, INC. and DUKE UNIVERSITY,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Action No. 12-cv-321**
	)	
WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., and WATSON PHARMA, INC.,	)	
	)	
Defendants.	)	

ANSWER AND DEFENSES OF WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., AND WATSON PHARMA, INC., AND COUNTERCLAIMS OF WATSON LABORATORIES, INC.

Defendants Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals"), Watson Laboratories, Inc., ("Watson Laboratories"), and Watson Pharma, Inc. ("Watson Pharma"), (collectively referred to herein as "Watson" or "Defendants"), by and through their attorneys, answer the Complaint for Patent Infringement of Plaintiff Allergan, Inc. ("Allergan") and Duke University ("Duke") (collectively "Plaintiffs"), with the following responses, defenses, counterclaims, and prayer for relief:

NATURE OF THE ACTION

1. In response to paragraph 1 of the Complaint, Watson admits only that the Complaint purports to state an action against Watson for alleged infringement of United States Patent Nos. 7,351,404 ("the '404 patent"), 7,388,029 ("the '029 patent"), 8,038,988 ("the '988 patent"), 6,403,649 ("the '649 patent"), and 8,017,655 ("the '655 patent") and that the Complaint avers that such alleged infringement is associated with Watson Laboratories' filing of

Abbreviated New Drug Application ("ANDA") No. 203749 with the U.S. Food and Drug Administration ("FDA"). Watson denies the remaining allegations of Paragraph 1.

THE PARTIES

2. In response to paragraph 2 of the Complaint, Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2, and therefore denies the allegations.

3. In response to paragraph 3 of the Complaint, Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3, and therefore denies the allegations.

4. In response to paragraph 4 of the Complaint, Watson admits that Watson Pharmaceuticals is a corporation organized and existing under the laws of the State of Nevada, and has a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ. Watson denies the remaining allegations of paragraph 6.

5. In response to paragraph 5 of the Complaint, Watson admits that Watson Laboratories is a corporation organized and existing under the laws of the State of Nevada. Watson denies the remaining allegations of paragraph 5.

6. In response to paragraph 6 of the Complaint, Watson admits that Watson Laboratories is a wholly-owned subsidiary of Watson Pharmaceuticals. Watson further admits that Watson Pharmaceuticals and Watson Laboratories share at least some common officers and at least one director. Watson denies the remaining allegations of paragraph 6.

7. In response to paragraph 7 of the Complaint, Watson admits that Watson Pharma is a corporation organized and existing under the laws of the State of Delaware. Watson denies the remaining allegations of paragraph 7.

8. In response to paragraph 8 of the Complaint, Watson admits that Watson Pharma is a wholly-owned subsidiary of Watson Pharmaceuticals. Watson further admits that Watson Pharmaceuticals and Watson Pharma share at least some common officers and at least one director. Watson denies the remaining allegations of paragraph 8.

JURISDICTION AND VENUE

9. In response to paragraph 9 of the Complaint, Watson admits that the Complaint purports to state an action for infringement of specified United States patents under certain titles of the United States Code specified in paragraph 9. Watson further admits that this Court has subject matter jurisdiction over certain of the claims asserted against Watson. Watson denies the remaining allegations of paragraph 9.

10. In response to paragraph 10 of the Complaint, Watson does not contest this Court's personal jurisdiction over Watson Laboratories for purposes of this action only, but otherwise denies the allegations contained therein.

11. In response to paragraph 11 of the Complaint, Watson does not contest this Court's personal jurisdiction over Watson Laboratories for purposes of this action only, but otherwise denies the allegations contained therein.

12. In response to paragraph 12 of the Complaint, Watson admits that Watson Laboratories is seeking regulatory approval of ANDA No 203749, and that upon regulatory approval of ANDA No 203749, intends to offer to sell and/or sell the products described in ANDA No 203749. Watson denies the remaining allegations contained therein.

13. In response to paragraph 13 of the Complaint, Watson denies the allegations contained therein.

14. In response to paragraph 14 of the Complaint, Watson admits the allegations contained therein.

15. In response to paragraph 15 of the Complaint, Watson denies the allegations contained therein

16. In response to paragraph 16 of the Complaint, Watson admits that Watson Pharma markets and sells in North Carolina and elsewhere in the United States drug products manufactured by Watson Laboratories. Watson denies the remaining allegations of paragraph 16.

17. In response to paragraph 17 of the Complaint, Watson admits that Watson Pharma offers products for sale in North Carolina and in this judicial district. Watson denies the remaining allegations of paragraph 17.

18. In response to paragraph 18 of the Complaint, Watson does not contest this Court's personal jurisdiction over Watson Laboratories for purposes of this action only, but otherwise denies the allegations contained therein.

19. Paragraph 19 of the Complaint states legal conclusions to which no answer is required. To the extent an answer is deemed required, Watson does not contest venue in this Court for this action, but otherwise denies the allegations contained therein.

THE PATENTS-IN-SUIT

20. Paragraph 20 of the Complaint states legal conclusions to which no answer is required. To the extent an answer is deemed required, Watson states that the '404 Patent speaks for itself, and denies the allegations of paragraph 20 to the extent that they deviate from or otherwise do not accurately reflect or describe the '404 Patent. Watson admits that a document purporting to be the '404 Patent is attached to the complaint, that the first page of the '404 Patent recites an issuance date of April 1, 2008 and a title of "Methods of Enhancing Hair Growth," but denies that the '404 Patent was duly and legally issued and otherwise denies the remaining allegations of paragraph 20.

21. In response to paragraph 21 of the Complaint, Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 21, and therefore denies all such allegations.

22. Paragraph 22 of the Complaint states legal conclusions to which no answer is required. To the extent an answer is deemed required, Watson states that the '029 Patent speaks for itself, and denies the allegations of paragraph 22 to the extent that they deviate from or otherwise do not accurately reflect or describe the '029 Patent. Watson admits that a document purporting to be the '029 Patent is attached to the complaint, that the first page of the '029 Patent recites an issuance date of June 17, 2008 and a title of "Compositions and Methods for Treating Hair Loss Using Non-Naturally Occurring Prostaglandins," but denies that the '029 Patent was duly and legally issued and otherwise denies the remaining allegations of paragraph 22.

23. In response to paragraph 23 of the Complaint, Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23, and therefore denies all such allegations.

24. In response to paragraph 24 of the Complaint, Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 24, and therefore denies all such allegations.

25. Paragraph 25 of the Complaint states legal conclusions to which no answer is required. To the extent an answer is deemed required, Watson states that the '988 Patent speaks for itself, and denies the allegations of paragraph 25 to the extent that they deviate from or otherwise do not accurately reflect or describe the '988 Patent. Watson admits that a document purporting to be the '988 Patent is attached to the complaint, that the first page of the '988 Patent recites an issuance date of October 18, 2011and a title of "Method of Enhancing Hair Growth,"

but denies that the '988 Patent was duly and legally issued and otherwise denies the remaining allegations of paragraph 25.

26. In response to paragraph 26 of the Complaint, Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26, and therefore denies all such allegations.

27. Paragraph 27 of the Complaint states legal conclusions to which no answer is required. To the extent an answer is deemed required, Watson states that the '649 Patent speaks for itself, and denies the allegations of paragraph 27 to the extent that they deviate from or otherwise do not accurately reflect or describe the '649 Patent. Watson admits that a document purporting to be the '649 Patent is attached to the complaint, that the first page of the '649 Patent recites an issuance date of June 11, 2002 and a title of "Non-Acidic Cyclopentane Heptanoic Acid, 2Cycloalkyl or Arylalkyl Derivatives as Therapeutic Agents," but denies that the '649 Patent was duly and legally issued and otherwise denies the remaining allegations of paragraph 27.

28. In response to paragraph 28 of the Complaint, Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 28, and therefore denies all such allegations.

29. Paragraph 29 of the Complaint states legal conclusions to which no answer is required. To the extent an answer is deemed required, Watson states that the '655 Patent speaks for itself, and denies the allegations of paragraph 29 to the extent that they deviate from or otherwise do not accurately reflect or describe the '655 Patent. Watson admits that a document purporting to be the '655 Patent is attached to the complaint, that the first page of the '649 Patent recites an issuance date of September 13, 2011 and a title of "Non-Acidic Cyclopentane

Heptanoic Acid, 2Cycloalkyl or Arylalkyl Derivatives as Therapeutic Agents," but denies that the '655 Patent was duly and legally issued and otherwise denies the remaining allegations of paragraph 29.

30. In response to paragraph 30 of the Complaint, Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 30, and therefore denies all such allegations.

31. In response to paragraph 31 of the Complaint, Watson Laboratories admits that the United States Food and Drug Administration's website indicates that Allergan is the Applicant for NDA No. 22369 for a bimatoprost ophthalmic solution, 0.03%, with the proprietary name Latisse®. Watson denies the remaining allegations of paragraph 31.

32. In response to paragraph 32 of the Complaint, Watson admits that the '404, '029, '988, '649, and '655 patents are listed in the Orange Book in connection with Latisse®. Watson denies the remaining allegations of paragraph 32.

33. Paragraph 33 of the Complaint states legal conclusions to which no answer is required. To the extent an answer is deemed required, Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 33, and therefore denies all such allegations.

ACTS GIVING RISE TO THIS ACTION FOR INFRINGEMENT OF THE PATENTS-IN-SUIT

34. In response to paragraph 34 of the Complaint, Watson admits that Watson Laboratories complied with statutory requirements (*see, e.g.*, 21 U.S.C. § 355(j)(2)(B)(ii), (iv); 21 C.F.R. § 314.95) and sent the required notice to Plaintiffs in a letter dated February 28, 2012 (the "Notice Letter"). Watson states that the Notice Letter speaks for itself, and denies the

allegations in paragraph 34 to the extent they deviate from or otherwise do not accurately reflect or describe the Notice Letter.

35. In response to paragraph 35 of the Complaint, Watson states that Watson Laboratories' ANDA No. 203749 speaks for itself, and denies the allegations of paragraph 35 to the extent that they deviate from or otherwise do not accurately reflect or describe ANDA No. 203749.

36. In response to paragraph 36 of the Complaint, Watson states that Watson Laboratories' ANDA No. 203749 speaks for itself, and denies the allegations of paragraph 36 to the extent that they deviate from or otherwise do not accurately reflect or describe ANDA No. 203749.

37. In response to paragraph 37 of the Complaint, Watson states that Watson Laboratories' ANDA No. 203749 speaks for itself, and denies the allegations of paragraph 37 to the extent that they deviate from or otherwise do not accurately reflect or describe ANDA No. 203749.

38. In response to paragraph 38 of the Complaint, Watson states that the Notice Letter speaks for itself and denies the allegations in paragraph 38 to the extent they deviate from or otherwise do not accurately reflect or describe the Notice Letter. Watson further states that the Notice Letter did not state that Watson Laboratories had included in its ANDA No. 203749 a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) as to the '649 or '655 patents. To the extent further response is deemed required, Watson denies the remaining allegations of paragraph 38.

39. In response to paragraph 39 of the Complaint, Watson admits that Watson Laboratories is pursuing FDA approval of ANDA No. 203749 seeking authorization to market

the products described in ANDA No. 203749. Watson denies the remaining allegations of paragraph 39.

40. In response to paragraph 40 of the Complaint, Watson admits that Watson Laboratories is pursuing FDA approval of ANDA No. 203749, and that upon FDA approval of ANDA No. 203749, Watson Pharma intends to offer to sell and/or sell the products described in ANDA No. 203749. Watson denies the remaining allegations of paragraph 40.

41. In response to paragraph 41 of the Complaint, Watson admits that Watson Laboratories is pursuing FDA approval of ANDA No. 203749 seeking authorization to market the products described in ANDA No. 203749. Watson denies the remaining allegations of paragraph 41.

42. In response to paragraph 42 of the Complaint, Watson admits that Watson Laboratories intends to continue to pursue FDA approval of ANDA No. 203749 and, upon FDA approval of ANDA No. 203749, Watson Pharma will distribute the products described in ANDA No. 203749 in the United States. Watson Laboratories denies the remaining allegations contained in paragraph 42.

43. In response to paragraph 43 of the Complaint, Watson admits that Watson Laboratories intends to continue to pursue FDA approval of ANDA No. 203749 and, upon FDA approval of ANDA No. 203749, Watson Pharma will distribute the products described in ANDA No. 203749 in the United States. Watson Laboratories denies the remaining allegations contained in paragraph 43.

COUNT I

(Infringement of the '404 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.03%)

44. In response to paragraph 44 of the Complaint, Watson incorporates by reference its responses to paragraphs 1-43 above as if fully stated herein.

45. In response to paragraph 45 of the Complaint, Watson admits that Watson Laboratories submitted ANDA No. 203749 to the FDA under 21 U.S.C. §§ 355(j)(1) and (2)(A) to obtain approval to engage in the commercial manufacture, use or sale of its proposed generic Bimatoprost Ophthalmic Solution, 0.03% throughout the United States. Watson denies the remaining allegations of paragraph 45.

46. In response to paragraph 46 of the Complaint, Watson denies the allegations contained therein.

47. In response to paragraph 47 of the Complaint, Watson denies the allegations contained therein.

48. In response to paragraph 48 of the Complaint, Watson denies the allegations contained therein.

49. In response to paragraph 49 of the Complaint, Watson denies the allegations contained therein.

COUNT II

(Declaratory Judgment of Infringement of the '404 Patent Under 35 U.S.C. §§ 271(a) and/or (b) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.03%)

50. In response to paragraph 50 of the Complaint, Watson incorporates by reference its responses to paragraphs 1-49 above as if fully stated herein.

51. In response to paragraph 51 of the complaint, Watson admits that Watson Laboratories submitted ANDA No. 203749 to the FDA under 21 U.S.C. §§ 355(j)(1) and (2)(A)

to obtain approval to engage in the commercial manufacture, use or sale of its proposed generic Bimatoprost Ophthalmic Solution, 0.03% throughout the United States. Watson denies the remaining allegations of paragraph 51.

52. In response to paragraph 52 of the Complaint, Watson denies the allegations contained therein.

53. In response to paragraph 53 of the Complaint, Watson denies the allegations contained therein.

54. In response to paragraph 54 of the Complaint, Watson denies the allegations contained therein.

55. In response to paragraph 55 of the Complaint, Watson denies the allegations contained therein.

56. In response to paragraph 56 of the Complaint, Watson denies the allegations contained therein.

57. Paragraph 57 of the Complaint states legal conclusions to which no answer is required. To the extent an answer is deemed required, Watson denies the allegations contained therein.

58. In response to paragraph 58 of the Complaint, Watson denies the allegations contained therein.

59. In response to paragraph 59 of the Complaint, Watson denies the allegations contained therein.

60. In response to paragraph 60 of the Complaint, Watson denies the allegations contained therein.

COUNT III

(Infringement of the '029 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.03%)

61. In response to paragraph 61 of the Complaint, Watson incorporates by reference its responses to paragraphs 1-60 above as if fully stated herein.

62. In response to paragraph 62 of the Complaint, Watson admits that Watson Laboratories submitted ANDA No. 203749 to the FDA under 21 U.S.C. §§ 355(j)(1) and (2)(A) to obtain approval to engage in the commercial manufacture, use or sale of its proposed generic Bimatoprost Ophthalmic Solution, 0.03% throughout the United States. Watson denies the remaining allegations of paragraph 62.

63. In response to paragraph 63 of the Complaint, Watson denies the allegations contained therein.

64. In response to paragraph 64 of the Complaint, Watson denies the allegations contained therein.

65. In response to paragraph 65 of the Complaint, Watson denies the allegations contained therein.

66. In response to paragraph 66 of the Complaint, Watson denies the allegations contained therein.

COUNT IV

(Declaratory Judgment of Infringement of the '029 Patent Under 35 U.S.C. §§ 271(a) and/or (b) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.03%)

67. In response to paragraph 67 of the Complaint, Watson incorporates by reference its responses to paragraphs 1-66 above as if fully stated herein.

68. In response to paragraph 68 of the Complaint, Watson admits that Watson Laboratories submitted ANDA No. 203749 to the FDA under 21 U.S.C. §§ 355(j)(1) and (2)(A)

to obtain approval to engage in the commercial manufacture, use or sale of its proposed generic Bimatoprost Ophthalmic Solution, 0.03% throughout the United States. Watson denies the remaining allegations of paragraph 68.

69. In response to paragraph 69 of the Complaint, Watson denies the allegations contained therein.

70. In response to paragraph 70 of the Complaint, Watson denies the allegations contained therein.

71. In response to paragraph 71 of the Complaint, Watson denies the allegations contained therein.

72. In response to paragraph 72 of the Complaint, Watson denies the allegations contained therein.

73. In response to paragraph 73 of the Complaint, Watson denies the allegations contained therein.

74. Paragraph 74 of the Complaint states legal conclusions to which no answer is required. To the extent an answer is deemed required, Watson denies the allegations contained therein.

75. In response to paragraph 75 of the Complaint, Watson denies the allegations contained therein.

76. In response to paragraph 76 of the Complaint, Watson denies the allegations contained therein.

77. In response to paragraph 77 of the Complaint, Watson denies the allegations contained therein.

COUNT V

(Infringement of the '988 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.03%)

78. In response to paragraph 78 of the Complaint, Watson incorporates by reference its responses to paragraphs 1-77 above as if fully stated herein.

79. In response to paragraph 79 of the Complaint, Watson admits that Watson Laboratories submitted ANDA No. 203749 to the FDA under 21 U.S.C. §§ 355(j)(1) and (2)(A) to obtain approval to engage in the commercial manufacture, use or sale of its proposed generic Bimatoprost Ophthalmic Solution, 0.03% throughout the United States. Watson denies the remaining allegations of paragraph 79.

80. In response to paragraph 80 of the Complaint, Watson denies the allegations contained therein.

81. In response to paragraph 81 of the Complaint, Watson denies the allegations contained therein.

82. In response to paragraph 82 of the Complaint, Watson denies the allegations contained therein.

83. In response to paragraph 83 of the Complaint, Watson denies the allegations contained therein.

COUNT VI

(Declaratory Judgment of Infringement of the '988 Patent Under 35 U.S.C. §§ 271(a) and/or (b) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.03%)

84. In response to paragraph 84 of the Complaint, Watson incorporates by reference its responses to paragraphs 1-83 above as if fully stated herein.

85. In response to paragraph 85 of the Complaint, Watson admits that Watson Laboratories submitted ANDA No. 203749 to the FDA under 21 U.S.C. §§ 355(j)(1) and (2)(A)

to obtain approval to engage in the commercial manufacture, use or sale of its proposed generic Bimatoprost Ophthalmic Solution, 0.03% throughout the United States. Watson denies the remaining allegations of paragraph 85.

86. In response to paragraph 86 of the Complaint, Watson denies the allegations contained therein.

87. In response to paragraph 87 of the Complaint, Watson denies the allegations contained therein.

88. In response to paragraph 88 of the Complaint, Watson denies the allegations contained therein.

89. In response to paragraph 89 of the Complaint, Watson denies the allegations contained therein.

90. In response to paragraph 90 of the Complaint, Watson denies the allegations contained therein.

91. Paragraph 91 of the Complaint states legal conclusions to which no answer is required. To the extent an answer is deemed required, Watson denies the allegations contained therein.

92. In response to paragraph 92 of the Complaint, Watson denies the allegations contained therein.

93. In response to paragraph 93 of the Complaint, Watson denies the allegations contained therein.

94. In response to paragraph 94 of the Complaint, Watson denies the allegations contained therein.

COUNT VII

(Infringement of the '649 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.03%)

95. In response to paragraph 95 of the Complaint, Watson incorporates by reference its responses to paragraphs 1-94 above as if fully stated herein.

96. In response to paragraph 96 of the Complaint, Watson admits that Watson Laboratories submitted ANDA No. 203749 to the FDA under 21 U.S.C. §§ 355(j)(1) and (2)(A) to obtain approval to engage in the commercial manufacture, use or sale of its proposed generic Bimatoprost Ophthalmic Solution, 0.03% throughout the United States. Watson denies the remaining allegations of paragraph 96.

97. In response to paragraph 97 of the Complaint, Watson denies the allegations contained therein.

98. In response to paragraph 98 of the Complaint, Watson denies the allegations contained therein.

99. In response to paragraph 99 of the Complaint, Watson denies the allegations contained therein.

100. In response to paragraph 100 of the Complaint, Watson denies the allegations contained therein.

COUNT VIII

(Declaratory Judgment of Infringement of the '649 Patent Under 35 U.S.C. §§ 271(a) and/or (b) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.03%)

101. In response to paragraph 101 of the Complaint, Watson incorporates by reference its responses to paragraphs 1-100 above as if fully stated herein.

102. In response to paragraph 102 of the Complaint, Watson admits that Watson Laboratories submitted ANDA No. 203749 to the FDA under 21 U.S.C. §§ 355(j)(1) and (2)(A)

to obtain approval to engage in the commercial manufacture, use or sale of its proposed generic Bimatoprost Ophthalmic Solution, 0.03% throughout the United States. Watson denies the remaining allegations of paragraph 102.

103. In response to paragraph 103 of the Complaint, Watson denies the allegations contained therein.

104. In response to paragraph 104 of the Complaint, Watson denies the allegations contained therein.

105. In response to paragraph 105 of the Complaint, Watson denies the allegations contained therein.

106. In response to paragraph 106 of the Complaint, Watson denies the allegations contained therein.

107. In response to paragraph 107 of the Complaint, Watson denies the allegations contained therein.

108. Paragraph 108 of the Complaint states legal conclusions to which no answer is required. To the extent an answer is deemed required, Watson denies the allegations contained therein.

109. In response to paragraph 109 of the Complaint, Watson denies the allegations contained therein.

110. In response to paragraph 110 of the Complaint, Watson denies the allegations contained therein.

111. In response to paragraph 111 of the Complaint, Watson denies the allegations contained therein.

COUNT IX

(Infringement of the '655 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.03%)

112. In response to paragraph 112 of the Complaint, Watson incorporates by reference its responses to paragraphs 1-111 above as if fully stated herein.

113. In response to paragraph 113 of the Complaint, Watson admits that Watson Laboratories submitted ANDA No. 203749 to the FDA under 21 U.S.C. §§ 355(j)(1) and (2)(A) to obtain approval to engage in the commercial manufacture, use or sale of its proposed generic Bimatoprost Ophthalmic Solution, 0.03% throughout the United States. Watson denies the remaining allegations of paragraph 113.

114. In response to paragraph 114 of the Complaint, Watson denies the allegations contained therein.

115. In response to paragraph 115 of the Complaint, Watson denies the allegations contained therein.

116. In response to paragraph 116 of the Complaint, Watson denies the allegations contained therein.

117. In response to paragraph 117 of the Complaint, Watson denies the allegations contained therein.

COUNT X

(Declaratory Judgment of Infringement of the '655 Patent Under 35 U.S.C. §§ 271(a) and/or (b) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.03%)

118. In response to paragraph 118 of the Complaint, Watson incorporates by reference its responses to paragraphs 1-117 above as if fully stated herein.

119. In response to paragraph 119 of the Complaint, Watson admits that Watson Laboratories submitted ANDA No. 203749 to the FDA under 21 U.S.C. §§ 355(j)(1) and (2)(A)

to obtain approval to engage in the commercial manufacture, use or sale of its proposed generic Bimatoprost Ophthalmic Solution, 0.03% throughout the United States. Watson denies the remaining allegations of paragraph 119.

120. In response to paragraph 120 of the Complaint, Watson denies the allegations contained therein.

121. In response to paragraph 121 of the Complaint, Watson denies the allegations contained therein.

122. In response to paragraph 122 of the Complaint, Watson denies the allegations contained therein.

123. In response to paragraph 123 of the Complaint, Watson denies the allegations contained therein.

124. In response to paragraph 124 of the Complaint, Watson denies the allegations contained therein.

125. Paragraph 125 of the Complaint states legal conclusions to which no answer is required. To the extent an answer is deemed required, Watson denies the allegations contained therein.

126. In response to paragraph 126 of the Complaint, Watson denies the allegations contained therein.

127. In response to paragraph 127 of the Complaint, Watson denies the allegations contained therein.

128. In response to paragraph 128 of the Complaint, Watson denies the allegations contained therein.

JURY TRIAL DEMAND

Plaintiffs' demand for jury trial is a legal statement to which no answer is required. To the extent an answer is deemed required, Watson denies that Plaintiffs are entitled to a trial by jury on any issue in this case.

DEFENSES

Without prejudice to the responses and denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not otherwise admitted, Watson asserts the following defenses:

FIRST AFFIRMATIVE DEFENSE

Watson does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, properly construed claim of United States Patent Nos. 7,351,404 ("the '404 patent"), 7,388,029 ("the '029 patent"), or 8,038,988 ("the '988 patent"), either directly, indirectly, contributorily, by inducement, or in any other manner.

SECOND AFFIRMATIVE DEFENSE

The claims of the '404, '029, and '988 patents are invalid for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, 112, and/or 116 thereof.

THIRD AFFIRMATIVE DEFENSE

Watson Pharma, Inc. and Watson Pharmaceuticals, Inc. are not proper or necessary parties to this suit.

FOURTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

FIFTH AFFIRMATIVE DEFENSE

On information and belief, by virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent application leading to the '404, '029, and '988 patents, Allergan and/or Duke are estopped from maintaining that any valid claim of the '404, '029, and '988 patents are infringed by Watson.

SIXTH AFFIRMATIVE DEFENSE

This Court lacks subject matter jurisdiction over all claims asserted by Plaintiffs against Watson regarding the '649 and '655 patents (Counts VII – X of Plaintiffs' Complaint), and over all claims asserted by Plaintiffs against Watson for declaratory judgment of infringement (Counts II, IV, VI, VIII and X of Plaintiffs' Complaint).

Watson expressly reserves the right to supplement and/or amend its Answer, including but not limited to supplementation and/or amendment of its defenses and amplifications of denials, as additional facts and information become known through the course of this case and discovery.

COUNTERCLAIMS

Defendant and Counterclaimant Watson Laboratories, Inc. ("Watson Laboratories"), asserts the following counterclaims against Plaintiffs and Counter-defendants Allergan, Inc. ("Allergan") and Duke University ("Duke"):

The Parties

1. Watson Laboratories, Inc. ("Watson Laboratories") is a corporation organized and existing under the laws of the State of Nevada, having a place of business at 400 Interpace Parkway, Parsippany, New Jersey.

2. On information and belief, Allergan is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

3. On information and belief, Duke University is an educational, research and healthcare institution and a North Carolina nonprofit corporation located in Durham, North Carolina.

Jurisdiction and Venue

4. Watson Laboratories' counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has subject matter jurisdiction over Watson Laboratories' counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Allergan and Duke because they have has availed themselves of the rights and privileges of this forum by suing Watson Laboratories in this District, and because Allergan and Duke conduct substantial business in, and has regular systematic contacts with, this District.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

Patents-in-Suit

8. Watson Laboratories is a pharmaceutical company and is engaged in the development and manufacture of pharmaceutical products.

9. Allergan purports to be the assignee of United States Patent No. 7,351,404 ("the '404 patent") entitled "Methods of Enhancing Hair Growth."

10. Duke purports to be the assignee of and Allergan purports to hold an exclusive field license for United States Patent No 7,388,029 ("the '029 patent") entitled "Compositions and Methods for Treating Hair Loss Using Non-Naturally Occurring Prostaglandins."

11. Allergan purports to be the assignee of United States Patent No. 8,038,988 ("the '988 patent"), entitled "Method of Enhancing Hair Growth."

12. On information and belief, Allergan is the purported owner of United States Patent No. 8,101,161 ("the '161 Patent"), entitled "Method of Enhancing Hair Growth."

13. Upon information and belief, Allergan is indicated in the records of the United States Food and Drug Administration as the holder of an approved New Drug Application ("NDA") No. 22369 for bimatoprost ophthalmic solution, 0.03%.

14. The '404, '029, '988 and '161 patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Latisse®.

15. Watson Laboratories filed Abbreviated New Drug Application ("ANDA") No. 203749 with the United States Food and Drug Administration ("FDA") seeking approval to manufacture, use, market, sell, and offer to sell generic bimatoprost ophthalmic solution, 0.03%.

16. On March 30, 2012, Plaintiffs sued Watson Laboratories in this judicial district alleging infringement of the '404, '029, and '988 patents, among others, in connection with Watson's Notice Letter.

17. Upon information and belief, Counterclaim Defendant Allergan is holding the '161 patent in reserve in order to file future infringement suits and further delay Watson's entry into the United States market for its ANDA products containing bimatoprost.

COUNT ONE: Declaratory Judgment of Non-Infringement of the '404 Patent (ANDA No. 203749)

18. Watson Laboratories re-asserts and re-alleges each of the foregoing paragraphs 1-17 of these counterclaims as if fully stated herein.

19. Allergan and Duke have accused Watson Laboratories of infringing claims of the '404 Patent in connection with ANDA No. 203749.

20. Watson Laboratories denies infringement of any valid, properly construed claim of the '404 Patent, and alleges that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Watson Laboratories' ANDA No. 203749 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '404 Patent.

21. There is an actual, substantial, and continuing justiciable case or controversy between Watson Laboratories on the one hand, and Allergan and Duke on the other, regarding infringement of the '404 Patent in connection with ANDA No. 203749.

22. Watson Laboratories is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the products that are the subject of Watson Laboratories' ANDA No. 203749 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '404 Patent either directly or indirectly.

COUNT TWO: Declaratory Judgment of Invalidity of the '404 Patent

23. Watson Laboratories re-asserts and re-alleges each of the foregoing paragraphs 1 - 22 of these counterclaims as if fully stated herein.

24. Allergan and Duke have accused Watson Laboratories of infringing claims of the '404 Patent.

25. Watson Laboratories denies infringement of the '404 Patent and alleges that the claims of the '404 Patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, 112, and/or 116.

26. There is an actual, substantial, and continuing justiciable case or controversy between Watson Laboratories on the one hand, and Allergan and Duke on the other, regarding the validity of the '404 Patent.

27. Watson Laboratories is entitled to a judicial declaration that one or more of the claims of the '404 Patent are invalid.

COUNT THREE: Declaratory Judgment of Non-Infringement of the '029 Patent (ANDA No. 203749)

28. Watson Laboratories re-asserts and re-alleges each of the foregoing paragraphs 1-27 of these counterclaims as if fully stated herein.

29. Allergan and Duke have accused Watson Laboratories of infringing claims of the '029 Patent in connection with ANDA No. 203749.

30. Watson Laboratories denies infringement of any valid, properly construed claim of the '029 Patent, and alleges that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Watson Laboratories' ANDA No. 203749 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '029 Patent.

31. There is an actual, substantial, and continuing justiciable case or controversy between Watson Laboratories, on the one hand, and Allergan and Duke on the other, regarding infringement of the '029 Patent in connection with ANDA No. 203749.

32. Watson Laboratories is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the products that are the subject of Watson Laboratories' ANDA No. 203749 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '029 Patent either directly or indirectly.

COUNT FOUR: Declaratory Judgment of Invalidity of the '029 Patent

33. Watson Laboratories re-asserts and re-alleges each of the foregoing paragraphs 1 - 32 of these counterclaims as if fully stated herein.

34. Allergan and Duke have accused Watson Laboratories of infringing claims of the '029 Patent.

35. Watson Laboratories denies infringement of the '029 Patent and alleges that the claims of the '029 Patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, 112, and/or 116.

36. There is an actual, substantial, and continuing justiciable case or controversy between Watson Laboratories, on the one hand, and Allergan and Duke on the other, regarding the validity of the '029 Patent.

37. Watson Laboratories is entitled to a judicial declaration that one or more of the claims of the '029 Patent are invalid.

COUNT FIVE: Declaratory Judgment of Non-Infringement of the '988 Patent (ANDA No. 203749)

38. Watson Laboratories re-asserts and re-alleges each of the foregoing paragraphs 1-37 of these counterclaims as if fully stated herein.

39. Allergan and Duke have accused Watson Laboratories of infringing claims of the '988 Patent in connection with ANDA No. 203749.

40. Watson Laboratories denies infringement of any valid, properly construed claim of the '988 Patent, and alleges that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Watson Laboratories' ANDA No. 203749 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '988 Patent.

41. There is an actual, substantial, and continuing justiciable case or controversy between Watson Laboratories on the one hand, and Allergan and Duke on the other, regarding infringement of the '988 Patent in connection with ANDA No. 203749.

42. Watson Laboratories is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the products that are the subject of Watson Laboratories' ANDA No. 203749 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '988 Patent either directly or indirectly.

COUNT SIX: Declaratory Judgment of Invalidity of the '988 Patent

43. Watson Laboratories re-asserts and re-alleges each of the foregoing paragraphs 1 - 42 of these counterclaims as if fully stated herein.

44. Allergan and Duke have accused Watson Laboratories of infringing claims of the '988 Patent.

45. Watson Laboratories denies infringement of the '988 Patent and alleges that the claims of the '988 Patent are invalid for failure to comply with one or more of the requirements

for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, 112, and/or 116.

46. There is an actual, substantial, and continuing justiciable case or controversy between Watson Laboratories on the one hand, and Allergan and Duke on the other, regarding the validity of the '988 Patent.

47. Watson Laboratories is entitled to a judicial declaration that one or more of the claims of the '988 Patent are invalid.

COUNT SEVEN: Declaratory Judgment of Non-Infringement of the '161 Patent (ANDA No. 203749)

48. Watson Laboratories re-asserts and re-alleges each of the foregoing paragraphs 1-47 of these counterclaims as if fully stated herein.

49. The '161 patent is listed in the FDA's Orange Book in connection with Latisse®. Watson Laboratories' Notice Letter asserted non-infringement and/or invalidity of claims of the '161 patent for the product described in Watson Laboratories' ANDA No. 203749, and noted that ANDA No. 203749 included a certification under 21 U.S.C. 355(j)(2)(A)(vii)(IV) of the Federal, Food, Drug, and Cosmetic Act with respect to the '161 patent. Watson Laboratories' Notice Letter accompanied an offer of confidential access to certain confidential information of Watson Laboratories.

50. Plaintiffs received Watson Laboratories' Notice Letter by no later than February 29, 2012, and Plaintiffs have not brought an action for infringement of the '161 patent against Watson Laboratories before the expiration of 45 days after the date on which Watson Laboratories' Notice Letter was received by Plaintiffs.

51. Watson Laboratories denies infringement of any valid, properly construed claim of the '161 Patent, and alleges that the manufacture, use, sale, offer for sale, or importation of the

products that are the subject of Watson Laboratories' ANDA No. 203749 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '161 Patent.

52. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Watson and Counterclaim Defendant Allergan concerning the infringement of the claims of the '161 patent in connection with ANDA No. 203749.

53. Pursuant to 21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5), Watson Laboratories is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the products that are the subject of Watson Laboratories' ANDA No. 203749 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '161 Patent either directly or indirectly.

COUNT EIGHT: Declaratory Judgment of Invalidity of the '161 Patent

54. Watson Laboratories re-asserts and re-alleges each of the foregoing paragraphs 1-53 of these counterclaims as if fully stated herein.

55. The '161 patent is listed in the FDA's Orange Book in connection with Latisse®. Watson Laboratories' Notice Letter asserted non-infringement and/or invalidity of claims of the '161 patent for the product described in Watson Laboratories' ANDA No. 203749, and noted that ANDA No. 203749 included a certification under 21 U.S.C. 355(j)(2)(A)(vii)(IV) of the Federal, Food, Drug, and Cosmetic Act with respect to the '161 patent. Watson Laboratories'

Notice Letter accompanied an offer of confidential access to certain confidential information of Watson Laboratories.

56. Plaintiffs received Watson Laboratories' Notice Letter by no later than February 29, 2012, and Plaintiffs have not brought an action for infringement of the '161 patent against Watson Laboratories before the expiration of 45 days after the date on which Watson Laboratories' Notice Letter was received by Plaintiffs.

57. Watson Laboratories denies infringement of any valid, properly construed claim of the '161 Patent, and alleges that the claims of the '161 Patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, 112, and/or 116.

58. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Watson and Counterclaim Defendant Allergan concerning the validity of the claims of the '161 patent in connection with ANDA No. 203749.

59. Pursuant to 21 U.S.C. § 335(j)(5)(C) and 35 U.S.C. § 271(e)(5), Watson Laboratories is entitled to a judicial declaration that one or more of the claims of the '161 Patent are invalid and that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Watson Laboratories' ANDA No. 203749 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '161 Patent.

WHEREFORE, Watson Pharma, Inc., Watson Pharmaceuticals, Inc., and Watson Laboratories, Inc. respectfully pray for judgment in their favor and against Plaintiffs as follows:

A. Declaring that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Watson Laboratories, Inc.'s ANDA No. 203749 have not infringed, do not infringe, and would not, if marketed, infringe any valid claim of the '404, '029, '988, and '161 patents;

B. Declaring that each claim of the '404, '029, '988, and '161 patents are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, 112, and/or 116;

C. Dismissing Plaintiffs' claims for declaratory judgment of infringement (Plaintiffs' Counts II, IV, VI, VIII, and X) with prejudice;

D. Dismissing Plaintiffs' claims regarding the '649 and '655 patents (Plaintiffs' Counts VII-X) with prejudice;

E. Dismissing Watson Pharma, Inc. and Watson Pharmaceuticals, Inc. with prejudice;

F. Ordering that Plaintiffs' Complaint be dismissed with prejudice and judgment entered in favor of Watson Laboratories, Inc.;

G. Declaring this case exceptional and awarding Watson Laboratories, Inc. its reasonable attorneys' fees and costs of defending this action and prosecuting its counterclaims under 35 U.S.C. § 285;

H. That Plaintiffs be estopped from asserting the '404, '029, '988, and '161 patents against Watson Laboratories, Inc.; and

I. That Plaintiffs take nothing and otherwise be denied all relief, and that Watson Laboratories, Inc. be awarded such other and further relief as the Court may deem just, equitable, and appropriate.

This the 24th day of April 2012.

/s/ H. Lee Davis, Jr.
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WATSON PHARMACEUTICALS, INC.,
WATSON LABORATORIES, INC., AND
WATSON PHARMA, INC.,

CERTIFICATE OF SERVICE

I hereby certify that on April 24, 2012, I electronically filed on behalf of the Defendants, Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Watson Pharma, Inc., the foregoing ANSWER AND DEFENSES OF WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC. AND WATSON PHARMA, INC. AND COUNTERCLAIMS OF WATSON LABORATORIES, INC. with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following persons. Further, this certifies that I electronically served the following persons:

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